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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/084,380	02/28/2002	Daniel G. Chain	P-4815-US1	3496

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EXAMINER	
CHERNYSHEV, OLGA N	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 02/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/084,380	CHAIN, DANIEL G.	
	Examiner	Art Unit	
	Olga N. Chernyshev	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-72* is/are pending in the application.

4a) Of the above claim(s) *26-48* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25 and 49-72* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/3/2*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group II in the reply filed on December 02, 2004 is acknowledged. The traversal is on the ground(s) that "[t]he mere fact that antibody that binds amyloid beta peptide can be used with the treatments of the invention does not affect the general nature of the system", and, further that the search for all groups together would not be burdensome on the Examiner (bottom at page 1 of the Response continuing to page 2).

Applicant's arguments have been fully considered and found to be persuasive in part. An application may properly be required to be restricted to one of two or more claimed inventions if they are able to support separate patents and they are either independent (MPEP § 806.04 - § 806.04 (j)) or distinct (MPEP § 806.05 - § 806.05 (i)). The Examiner has shown that the Groups (I, II) and III are independent or distinct for the reasons in the previous Office action (see Paper mailed on July 14, 2004). Furthermore, MPEP § 803 provides that the separate classification (i.e., class and subclass) of distinct inventions is sufficient to establish a *prima facie* case that the search and examination of the plural inventions would impose a serious burden upon the Examiner; such separate classification was set forth in the Office action mailed on July 14, 2004. However, with respect to inventions of Groups I and II, the restriction between these two groups has been reconsidered and the claims of Groups I and II have been rejoined.

The requirement is made FINAL.

Claims 26-48 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Applicant timely traversed the restriction (election) requirement in the reply filed on December 02, 2004.

Claims 1-25 and 49-72 are under examination in the instant office action.

Sequence compliance

2. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821 (a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. § 1.821 through 1.825. Specifically, no sequence listing has been provided which includes the amino acid sequences presented on pages 16, 18, 27 and 28 of the instant specification. In case these sequences are new, Applicant needs to provide a substitute computer readable form (CRF) copy of a "Sequence Listing" which includes all of the sequences that are present in the instant application and encompassed by these rules, a substitute paper copy of that "Sequence Listing", an amendment directing the entry of that paper copy into the specification, and a statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. § 1.821 (e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d). The instant specification will also need to be amended so that it complies with 37 C.F.R. § 1.821(d) which requires a reference to a particular sequence identifier (SEQ ID NO:) be made in the specification and claims wherever a reference is made to that sequence. See M.P.E.P. 2422.04.

Claim Objections

3. Claim 13 is objected to because of the following informalities: Claim 13 has a period in the middle of the claim, see MPEP 608.01 (m). Appropriate correction is required.

4. Claims 49-72 are objected to for being dependent from the non-elected claims. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 6, 12-25, 51-52, 55-56, 59-60, 63-64, 67-68 and 71-72 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claims 6, 12, 19 and 25 are vague and indefinite for recitation "bispecific antibody". The metes and bounds of the recitation cannot be determined from the claims or the instant specification. Clarification is required.

7. Claim 13 is vague and ambiguous for recitation "Alzheimer's disease associated with Down Syndrome". The metes and bounds of the recitation cannot be determined from the claims or the instant specification. Clarification is required.

8. Claims 14, 20, 51-52, 55-56, 59-60, 63-64, 67-68 and 71-72 are vague and indefinite for recitation "inhibiting or suppressing the accumulation [or neurotoxicity]". There appears to be no evident difference between "inhibition" and "suppression", which seem to be synonymous terms.

9. Claims 20, 52, 56, 60, 64, 68 and 72 are further indefinite and ambiguous for recitation "delaying [...] the neurotoxicity". The process of "delaying of neurotoxicity" is not clearly

defined or explained in the instant specification, as filed, and, therefore, the clear meaning of the process is not obvious.

10. Claims 14-25, 51-52, 55-56, 59-60, 63-64, 67-68 and 71-72 are vague and ambiguous as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the claims recite methods of suppressing the accumulation or neurotoxicity without any reference or relation to a subject or place of accumulation or neurotoxicity of amyloid beta. Further, it is not obvious where or to whom the antibody is intended to be administered. Clarification is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-13 and 49-50, 53-54, 57-58, 61-62, 65-66 and 69-70 are rejected under 35 U.S.C. 102(b) as being anticipated by Schenk, 1999 (WO 99/27944).

Applicant is advised that with regards to the priority date, the effective filing date of the instant application is considered to be the filing date of 02/28/2002. The instant application is a continuation-in-part of earlier applications 09/402,820 and 60/041,850. The instant claimed invention is directed to methods of treatment of amyloidogenic diseases or disorders by administration of antibodies to Aβ, and this invention is first disclosed and claimed only in the instant application, while the earlier applications are directed to a different subject matter, such

as treatment of Alzheimer's disease by methods of administration of recombinant DNA molecule.

Claims 1-6, 49, 53, 57, 61, 65 and 69 are directed to methods of treating a subject having Alzheimer's disease by administration of an antibody to Aβ. Claims 7-13, 50, 54, 58, 62, 66 and 70 are directed to methods f treating a subject having a disease characterized by amyloid beta deposition by administration of an antibody to Aβ. Document of Schenk discloses methods for treatment of amyloidogenic diseases (diseases that are characterized by amyloid beta deposition, which include Alzheimer's disease, see abstract and pages 1 and 13, for example) by administration of a suitable agent, such as an antibody to Aβ peptide (see abstract and bottom at page 13). Further, document of Schenk specifically discloses antibodies to Aβ that could be used for administration. Such antibodies include antibodies to Aβ (bottom at page 17), monoclonal, humanized (page 18), chimeric and Fv or F(ab) antibodies (page 19). Also, amyloid β peptide of Schenk includes a peptide of 39-43 amino acids (page 14), as well as "an active fragment or analog of a natural Aβ peptide" (top at page 15) and fragments from N-terminal half of Aβ and modifications of N or C terminal amino acids (page 15, first paragraph). Thus, antibodies to Aβ of Schenk encompass antibodies directed to different molecular variations of Aβ, which also includes fragments of "amyloid precursor protein". Thus, document of Schenk fully anticipate the instant claims 1-13 and 49-50, 53-54, 57-58, 61-62, 65-66 and 69-70.

Double Patenting

12. Applicant is advised that should claims 1, 7, 14, 20, 49, 50, 51 and 52 be found allowable, claims 2, 8, 15, 21, 3, 9, 16 and 22, respectively, will be objected to under 37 CFR

1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Conclusion

13. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C. Caputa can be reached on (571) 272-0829. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 872-9306. If this number is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (571) 273-0870. Official papers should NOT be faxed to (571) 273-0870.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Olga N. Chernyshev, Ph.D.
Primary Examiner
Art Unit 1646

February 8, 2005